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March 2, 2000

Charles J. Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Warner-Lambert's Requests for Exemption

Dear Dr. Ganley:

I am Divisional Vice President, Merchandising HBA/OTC at Kmart, and on behalf of Kmart, I am writing to respond to an issue raised by Warner-Lambert with respect to FDA's Final Rule on Over-the-Counter Labeling, 21 CFR § 201.66 (the "Final Rule"). Warner-Lambert representatives have informed me that unless their Requests for Exemption are granted by FDA, they will be required to seek alternative packaging for the following products that are carried by Kmart: Benadryl® Allergy/Sinus Headache (Gelcaps 24's), Benadryl® Allergy/Sinus Headache (Caplets 24's), Benadryl® Allergy/Sinus Headache (48's), Benadryl® Itch Stopping Gel (Regular), Benadryl® Itch Stopping Gel (Max. Strength), Benadryl® Spray (2%), Caladryl Clear® (6 oz.), Sinutab® Max. Strength Sinus Allergy (24's), Sudafed® Severe Cold (12's), Sudafed® Cold & Cough Liquid Caps (20's), and Zantac 75® (4's). These packaging changes potentially include the use of blister cards, extended text labeling, fifth panels or fold down panels, and increased package sizes. Since such changes in packaging will affect Kmart, Warner-Lambert has asked for our feedback should these changes be required.

Kmart fully supports the purpose and intent of the Final Rule. There are potential benefits for our customers from labels for OTC drug products in the new format. We also believe, however, that allowing modest deviations from the Final Rule will benefit the consuming public to a greater extent than will requiring Warner-Lambert to seek alternative packaging for certain products that cannot comply with the format requirements of the Final Rule.

We are familiar with the above mentioned SKU's for which Warner-Lambert is seeking exemptions, and we are unaware of any complaints from consumers regarding the readability or legibility of such products. In fact, we believe that these products do convey all the requisite label information in a readable manner.

Moreover, denying Warner-Lambert's exemption requests and thereby requiring alternative packaging for SKU's that cannot comply with the Final Rule is impractical. Changes in packaging to any product affects Kmart by potentially requiring changes in case packs, pallet configurations, case weights, various internal systems, and shelf space specifications, and may potentially lead to the loss of the individual SKU to the consumer. The consumer will ultimately bear the cost of these changes by an increase in price, being forced to purchase a larger SKU, being forced to purchase more of the product than desired, or by a lack of availability of particular products. Such costs, as well as time and effort, would be needlessly incurred given that the deviations from the Final Rule requested by Warner-Lambert's exemption requests would still result in products with readable labels.

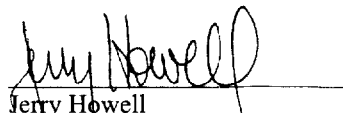
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The impracticality of denying Warner-Lambert's exemption requests is exacerbated by the fact that the significant costs that would be incurred by Kmart surely outweigh the negligible impact on the consuming public should Warner-Lambert's exemption requests be granted. Only 12% of the total Warner-Lambert SKU's carried by Kmart would potentially require exemption requests. Therefore, allowing minor deviations from the Final Rule in order to accommodate such few products and speed their entry into the marketplace is warranted given the minimal exposure of such "exempted" SKU's. Most importantly, for the consumers that do rely on these particular SKU's, the denial by FDA of modest deviations from the Final Rule surely is not worth the increased cost, inconvenience, and potential loss altogether of these products that would result.

In sum, we support Warner-Lambert's Requests for Exemption. Should you wish to discuss the matter further, do not hesitate to contact me.

Yours truly,

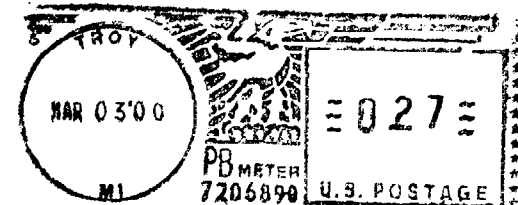
A handwritten signature in black ink, appearing to read "Jerry Howell", written over a horizontal line.

Jerry Howell
Divisional Vice President, Merchandising HBA/OTC

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PRESORTED
FIRST CLASS



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